AD_____ "

Award Number:
W81XWH-06-2-0031

TITLE:
Diabetes Care and Treatment Project: A Diabetes Institute of the Walter Reed
Health Care System and Joslin (and University of Hawaii) Telemedicine
Initiative

PRINCIPAL INVESTIGATOR:
Robert A. Vigersky, COL MC

CONTRACTING ORGANIZATION:
T.R.U.E Research foundation
San Antonio, TX 78217

REPORT DATE:
April 2010

TYPE OF REPORT: Ô↔^á→ÁNääæ^ä|↑

PREPARED FOR: U.S. Army Medical Research and Materiel Command
               Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

     X Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE *(DD-MM-YYYY)* 01-04-2010	2. REPORT TYPE Final Addendum	3. DATES COVERED *(From - To)* 10 Mar 2009 - 9 Mar 2010

4. TITLE AND SUBTITLE

Diabetes Care and Treatment Project: A Diabetes Institute of the Walter Reed Health Care System and Joslin (and University of Hawaii) Telemedicine Initiative

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-06-2-0031

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Robert A. Vigersky, COL MC

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) AND ADDRESS(ES)

T.R.U.E Research foundation
San Antonio, TX 78217

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT The major goals of this continuing project are the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients the care process, that empowers the patient to better manage their disease, that can be performed a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research was to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. The need for diabetes disease management is driven by the knowledge that diabetes is not currently curable, but it is treatable, and its complications are preventable. The primary goal of treatment is to enable people with diabetes to live healthy lives.

15. SUBJECT TERMS

>cg`]b˙J]g]cb˙BYħk cf_žhŕ˙Ya YX]WɉoYžX]UˇVYħŕg˙a Y`]ħi gžX]UˇVYħWfYħ]bcdUħ mžWᶜa dfŕ\ Ybg]j Y˙`X]UˇVYħŕg˙a UbU[ Ya Ybħž X]UˇVYħg˙Wﬞgˇa UbU[ Ya Ybħ žX]UˇVYħŕg˙VY\ Uj ]cfU˙UggYgga Ybħhcc`

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	**b. ABSTRACT** U	**c. THIS PAGE** U	UU	41	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

Table of Contents

Introduction

Diabetes Mellitus (DM) is a prevalent costly condition that causes significant morbidity and mortality. In the United States nearly 24 million people or 7.8% of the total population have diabetes and of whom at least 5.7 million are undiagnosed. An additional 54 million people are estimated to have pre-diabetes.   Diabetes has recently been identified as the fifth leading cause of death in the United States (2). Consistent with devastating personal effects of diabetes, the costs to the health care system were estimated at $174 billion in 2007 ($116 billion in direct medical costs and $58 billion in reduced national productivity (1). People with diagnosed diabetes, incur average expenditures of $11,744 per year, of which $6,649 is attributed to diabetes. People with diagnosed diabetes, on average, have medical expenditures that are more than twice the amount of expenditures in the absence of diabetes (http://diabetes.niddk.nih.gov/DM/PUBS/statistics/).There is abundant evidence and documentation that diabetes is a major component of all health care expenditures in the United States with most of this cost associated with long term complications of diabetes specifically, retinopathy, nerve damage (neuropathy), heart disease, stroke, kidney failure, and peripheral vascular disease resulting in amputations (. Furthermore, the actual national burden of diabetes is likely to exceed the $174 billion estimate because it omits the social cost of intangibles such as pain and suffering, care provided by nonpaid caregivers, and excess medical costs associated with undiagnosed diabetes.

Traditional health care delivery systems involve individual providers reacting to patient-initiated complaints and visits. Care is often fragmented, disorganized, duplicative, and focused on managing established diseases and complications. Management of the disease is provider directed and focuses on pharmacologic and technologic interventions with little attention to patient self-management behaviors and provider-patient interactions (6). Evidence shows that improving care for diabetic patients results in cost savings for health care organizations and recent economic analysis studies have shown that diabetes eye care and preconception care were found to be cost saving as was preventing neuropathy and improving glycemic control.

Despite advances in treating these complications, efforts aimed at prevention are the best approach to reduce morbidity and mortality. In the last decade, innovative interventions for health care delivery have emerged that show promise for improving care, outcomes and costs for individuals and populations with diabetes. Disease and case management are two interventions that continue to demonstrate considerable potential and promise. In the arena of prevention, objectives 5-11 through 5-15 of the *Healthy People 2010* for the United States directly relate to improving screening for complications involving the retina, the kidney, the extremities, the oral cavity and the monitoring of glycemic control.

Two problems to overcome in order to reduce or prevent diabetic complications are (1) providing access of all diabetic patients to proven diagnostic and treatment strategies which reduce the risk of vision loss and (2) identifying effective methods to improve the metabolic control of patients with diabetes to reduce the risk of chronic complications. The challenge to overcome these problems is formidable. For example, intensive research over the last 30 years has developed methods that virtually eliminate diabetic retinopathy as a cause of severe vision loss. Nevertheless, diabetes remains the leading cause of new blindness in working-aged adults in the United States (1). The reason for this incongruity is many patients do not receive quality eye care because of geographical barriers, insufficient health insurance or financial resources, or patient or health care provider ignorance.

In a review article aimed at examining the effectiveness of disease management and case or care management for people with diabetes, the authors found that disease and care management was effective as interventions when delivered concurrently and also when delivered in conjunction with educational interventions, decision support and reminders on performance issues, such as, timely retinal evaluation. These authors went on to indicate that one of the most pressing needs is to better define effective interventions as disease management has multiple component interventions. It may be that for the optimal use of resources only the interventions that contribute the most to positive outcomes need to be implemented. These interventions have yet to be defined. Additional research will need to be done, however, to identify the optimal intensity and frequency of these interventions as well as a consideration of whether professionals other than nurses (social workers, health aids or pharmacists) can function as care mangers. Other research areas of importance were identified as: consideration of integration of disease management into existing health care systems, the effect of disease and care management on long-term health and quality of life outcomes, such as, cardiovascular disease events, visual impairment, amputations, renal failure and mortality, and the effect of care management on blood pressure, weight, lipid levels and provider screening rates for retinopathy, peripheral neuropathy and microalbuminuria. Finally this review was unable to identify any appropriately rigorous studies aimed at evaluating the cost effectiveness of the care management intervention.

Overview

This annual report for the ongoing JVN Telehealth program at WRAMC provides an overview and status report of the studies designed to address the research questions posed above. This telehealth initiative is a unique opportunity to leverage the technological developments achieved over the past 5 years in the development of the JVN eye care and disease management programs to provide evaluations of the multiple diabetes disease management interventions from a single unified platform, the JVN Comprehensive Diabetes Management Program. The implementation of the JVN programs is extraordinarily timely in light of a recent publication in the Journal of the American Medical Association promoting the use of organized care management processes to improve the health care quality for patients with chronic diseases. The authors conclude that, although the use of care management processes vary greatly among physician organizations, the usage is low on average. They call on government and private purchasers of health care to increase the usage of care management processes through provision of external incentives for improvement of health care quality and to promote and assist physician organization to increase or improve their information technology capabilities. This continuation proposal is positioned to allow participants to play a lead role in developing evidence from rigorous multi-center studies to further support these recommendations.

The research proposals described below will leverage the successful deployment of the Joslin Vision Network (JVN) Eye Health Care program and the integration of the Comprehensive Diabetes Management Program (CDMP) to provide continuum of care for diabetic patients. The CDMP application has been developed under this collaboration and represents participation and input from leading experts in diabetes care from the Joslin Diabetes Center, Department of Defense, and the Veterans Health Administration.

Various studies have been deemed critical in order to provide the medical evidence to support preliminary data and expectations that this program will provide significant reductions in health care dollar expenses while maintaining a high quality of care as assessed through a reduction in

complications such as blindness from diabetes. The expectation is that the use of this program will also increase the access of patients to appropriate care and provide a very powerful tool that will empower the patient to improve their own management of their diabetes.

The studies proposed in this continuing proposal are prospective in nature and involve multiple participating centers. There are 8 different research projects associated with the Joslin/University of Hawaii *research program* (as distinct from the research related to the development of new CDMP functionality) taking place across 4 sites. As shown in the table below, four of these research projects are taking place at Walter Reed. The study designs across the four Walter Reed projects vary from each other. Two are observational studies (those designed to assess the test-retest reliability of the BAT), one is a randomized clinical trial that will provide prospective data for insertion into decision models (the JVN cost efficiency study), and one is pre-/post- usability test of the implementation of the CDMP in the Diabetes Institute at Walter Reed (CDMP usability/workflow study). The specifics of the study designs are described in the attached Statements of Work.

User evaluations of the Study Manager Module are not a scientific aim and therefore do not have a study associated with them. Rather, Walter Reed has been using the Study Manager Module more than any other site, for the projects enumerated here as well as others, and we have been refining it as we gain experience with this tool.

Research Studies by Site

	Site				
Project	Joslin	Hawaii	WRAMC	VA	Status
Prospective cost efficiency study performed using the Telehealth Eye Care Module			√		Recruitment completed, data completion anticipated 30 June 2010
Prospective risk benefit study using the Telehealth Eye Care Module				√	Recruitment ongoing
Human Factors study of the CDMP: Usability Lab	√				Complete; Manuscript published
CDMP usability and impact on clinical workflow study			√		Data collection and analyses completed
Prospective clinical outcomes efficacy and cost efficiency study using the CDMP (aka Internet-based Diabetes Education and Case Management)				√	Data collection complete and the last subject has completed the protocol; analyses ongoing
An Assessment of the Test-Retest Reliability of the CDMP BAT	√	√	√		Data collection complete at Joslin, VA, WRAMC. HI has ceased data collection due to lack of funds. Combined analyses of Joslin and WRAMC

					data was conducted at WRAMC. Data analysis demonstrated poor correlation between activity and food (r = 0.4). Manuscript combining the BAT reliability and validity studies is in progress.

An Assessment of the Validity of the CDMP BAT	√	√	√		Recruitment completed at WRAMC and was discontinued at HI, therefore only subjects enrolled at WRAMC will be included in predictive validity. Activity and food logs coded by HI; all data analyzed by WRAMC. Manuscript combining the BAT reliability and validity studies is in progress.
Additional Human Factors Study for the CDMP Application: Expert Review of the CDMP	NA	NA	NA	NA	Completed; suggested changes to CDMP incorporated

Notes: NA means not applicable. The Expert Review of the CDMP did not require recruiting subjects and was done by employees of the American Institutes for Research at their offices.

Statement of Work and Key Research Accomplishments

The different studies and progress since FY06 are enumerated below:

1. Prospective multi-center cost efficiency study performed using the JVN Telehealth Eye care module

DESCRIPTION:
The primary questions are: What are the costs associated with diabetic retinopathy evaluations performed by an ophthalmologist or optometrist with a dilated eye examination and the JVN system using digital video imaging through an undilated pupil? What is the cost-effectiveness of ophthalmoscopy performed by eye care professionals compared to the Joslin Vision Network?

Specifically, the purpose of this study is to compare the costs and cost-effectiveness of the Telehealth Eye Care module with conventional clinic-based eye examinations among a diabetic cohort receiving annual eye examinations. The Eye Care Module is a digital teleophthalmology system developed by the Beetham Eye Institute at the Joslin Diabetes Center in cooperation with the Departments of Defense and Veterans Affairs. The research design for this study is a randomized clinical trial that will provide prospective data for insertion into decision models. In turn, the decision models will generate

the data to evaluate the cost-effectiveness of the Eye Care Module versus conventional clinic-based eye examinations. Consenting patients (n = 360) at sites of the Walter Reed Army Health Care System (WRHCS) with type 1 or type 2 diabetes mellitus and scheduled for eye examinations on an annual basis were enrolled in the study and randomized to conventional clinic-based eye examinations or eye examinations performed by the Telehealth Eye Care Module (plus an assessment of visual acuity). Subjects were followed for one year. The study will track all costs that accrue over that year in the provision of care for both modalities, including labor, equipment, travel for the study subjects, and lost wages/productivity for study subjects, among others. Cost-effectiveness will be measured based on study subjects' compliance with the clinical eye examination and follow-up recommendations and diagnostic and treatment outcomes. We will *a priori* generate cost-effectiveness data based on diagnoses of diabetic retinopathy and macular edema. In a cost consequence analysis, we will consider other diagnostic outcomes and outcomes in aggregate. Additionally, we will impute cases of expected vision loss and, therefore, project differences in the number of cases of vision loss averted between modalities.

PROGRESS:
Rigorous study design completed. The study protocol was written and approved by the Walter Reed Army Medical Center (WRAMC) Human Use Committee (HUC)/IRB. JVN retinal imaging workstations were located at WRAMC, KACC, DeWitt, and the Fairfax Family Health Center. Two retinal reading stations were located in the WRAMC Department of Ophthalmology and the KACC Department of Optometry. Recruitment began in September, 2006. An addendum to increase the target enrollment from 243 to 393 was approved by WRAMC HUC in January, 2008. The addendum was submitted due to the rate of ungradable images taken in the JVN study arm which, at the beginning of the study, was substantially higher than the expected rate of 10-15%, thus necessitating an increase in enrollment in order to achieve statistical power.

Reasons for the comparatively high ungradable rate early in this study have been resolved and recruitment has been completed at all four sites for a total of 360 enrolled subjects at all four sites.

The original study on which this particular protocol is based was recognized as the best paper publication in the journal of *Telemedicine and e-Health* for 2006 (Whited JD, Datta SK, Aiello LM, Aiello LP, Cavallerano JD, Conlin PR, Horton MB, Vigersky RA, Poropatich RK, Challa P, Darkins AW, Bursell SE: A modeled economic analysis of a digital teleophthalmology system as used by three federal healthcare agencies for detecting proliferative diabetic retinopathy. *Telemedicine and e-Health.* 2005;11, 641-651.

MILESTONES AND DELIVERABLES:
Completion of data collection and completion of initial data analyses for presentation at an annual meeting (TBD). Ultimately we hope to publish our findings and deploy the JVN telehealth eye care module throughout military treatment facilities (MTFs) and civilian clinics in the United States and abroad, thus providing an effective and economic means of screening retinal eye disease in medically underserved areas.

2. The Usability and Workflow Impact on Diabetes Care Specialists of the Comprehensive Diabetes Management Program (CDMP).

DESCRIPTION:
This project examined the usability and impact on clinical workflow of the Comprehensive Diabetes Management Program (CDMP). The CDMP is an, interactive, web-based tool for physicians, care managers and people with diabetes. The

project examined the CDMP's usability and impact on clinical workflow by comparing them to those of the existing, baseline health information system in the Walter Reed Army Health Care System (WRHCS). Specifically, we examined the Diabetes HealtheCard data (which documents the process and quality measures of the Diabetes Quality Improvement Program (DQIP)) of selected diabetes health care providers and administered several different questionnaires regarding the usability of the diabetes care system before and after adoption of the CDMP. We also conducted structured focus group discussions with the providers lead by a trained, experienced facilitator. Health care providers selected for this study were the Nurse Practitioners (NPs) of the Diabetes Institute of the Walter Reed Health Care System (not just Walter Reed Army Medical Center). All of the recruiting, data collection, and data analyses were done through a contract with the American Institutes for Research so as to minimize coercion of the study participants and maintain objectivity.

PROGRESS:
Data collection, including a structured focus group discussion with the providers lead by a trained, experienced facilitator, was completed by March 2007. Three reports from this study – corresponding with the three main types of data collected were completed and circulated by the American Institutes for Research in June 2007.

In September, 2008, the "architects" of CDMP (Sven Bursell, Stephanie Fonda, and Estenda Solutions (Drew Lewis & Richard [RJ] Kedziora) held an additional focus group with the DI nurse practitioners to re-assess usability of the program. The findings confirmed those of the initial focus group that the program was visually appealing and overall had appropriate content, but needed improvement in navigation and terminology. A theme that occurred throughout both focus groups was that CDMP is a tool for managing diabetes from a generalist or case manager perspective versus a specialized diabetes practitioner. Suggestions to enhance the usability and efficiency of the program are being used to revise CDMP.

    Publications:
1. Fonda SJ et al. (2008). Usability Test of an Internet- Based Informatics Tool for Diabetes Care Providers: the comprehensive Diabetes Management Program. Diabetes Technology and Therapeutics, **10**(1), 16-24.

2. Fonda SJ, Birkmire-Peters D, Bursell, SE (2008). Comprehensive Diabetes Management Program (CDMP). In R. Merrell and R.A. Cooper (Eds.), Proceedings of the Fourth IASTED International Conference on Telehealth and Assistive Technologies, 619 - 807: 168-173. Calgary: ACTA Press.

MILESTONES AND DELIVERABLES:
As this is just one component of a multi-factored and ongoing project, the findings are being used to further refine and develop CDMP as a tool to enhance case managers and primary care providers' management of patients with diabetes.

3 and 4. Clinical Validation of the Behavior Assessment Tool (BAT) developed for the CDMP application (including test-retest reliability and validity).

The Behavioral Assessment Tool (BAT) was developed as a stand-alone module within the CDMP. It is a screening questionnaire containing questions about psycho-social factors, nutrition, physical activity, alcohol and tobacco use, medications, general health, self-monitoring of blood glucose and economic factors. There are two studies associated with testing its reliability and validity An Assessment of the Test-Retest Reliability of the CDMP BAT and An

Assessment of the Validity of the CDMP BAT.

DESCRIPTION:
The reliability assessment was a multi-site observational study with two measurements per study subject taking place 2 to 4 weeks apart. The original sites were: the VA Boston Healthcare System (n = 42), Joslin Diabetes Center (n = 43 – with the additional subject being approved by the IRBs), Walter Reed Army Medical Center (n = 42), and community health centers in Hawaii (n = 42), however, due to unexpected challenges in recruitment at the community health centers, recruitment was discontinued in Hawaii. The study is explained in detail in the Annual Report dated 30 April 2009.

PROGRESS:
The VA, Joslin, and Walter Reed have completed all data collection. We presented a poster of the results for the Joslin site at the CDC Diabetes Translation Conference (Garren, J, Fonda, SJ, Bursell, SE, Conlin, PR, Vigersky RA, Birkmire-Peters D). Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes. Poster presented at the CDC Diabetes Translation Conference, Atlanta, April - May 2007).

MILESTONES AND DELIVERABLES:
Analyses of the data from WRAMC and Joslin has been completed by Dr. Stephanie Fonda at WRAMC and a publication describing the implementations, findings and recommendations of the BAT reliability and validity studies is in preparation.

DESCRIPTION:
The validity assessment was also a multi-site observational study. that examined concurrent and predictive validity –. Concurrent validity was measured by examining how study subjects' responses to its questions correlate with a) their responses to similar questions in other questionnaires administered at the same time, b) recent self-report physical activity and food "logs", c) a cotinine test (to assess smoking status), and d) concurrent health-related factors obtained from their medical records, including current or recent hemoglobin A1c (A1c), current or recent Body Mass Index (BMI), current prescribed medications, and current health conditions. Predictive validity was measured by assessing how study subjects' responses to BAT questions correlate with their future health-related factors, namely health-related factors at six months and twelve months after the BAT administration completed at the beginning of the study as part of Objective 1. The health-related factors examined included: new A1c; new BMI; adherence to recommended foot and eye exams in the intervening period; number of hospitalizations, number of hospital days, and number of emergency room visits in the intervening period; new medications; frequency of provider use and type of provider use in the intervening period; and new health conditions.

PROGRESS:
Data collection for this study is complete at Joslin and at WRAMC. Joslin enrolled 72 subjects: 63 completed the study and 9 either dropped out or were lost to follow-up. WRAMC enrolled 75, 62 subjects completed the study. Similar to the BAT reliability study, recruitment was discontinued in Hawaii as a result of unexpected challenges in recruitment at the community health centers. Investigators at University of Hawaii coded the activity and food logs for data analysis.

MILESTONE AND DELIVERABLES:
Analyses of the data has been completed. A publication describing the implementations, findings and recommendations of the combined BAT studies is in preparation.

5. Deployment of JVN Telehealth CDMP application into the Department of Defense HealtheForces. Robert Vigersky MD, and Sven-Erik Bursell PhD.

PROGRESS:
Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005. Diabetes Institute staff at WRAMC received CDMP training in June 2005. The Diabetes Institute staff is currently developing the process and procedures for use of the CDMP in their clinic and the Usability/Workflow Study has been completed and findings are being used to further refine CDMP as a case management tool (see #2 above). Recent requirements regarding interfacing to CHCSII are currently being investigated. A three-stage plan for integration which was initiated after discussions with representatives of the Office of the Surgeon General of the Army is being modified to be consistent with the Common Development Environment (CDE) being developed by TATRC as a platform for the integration of clinical programs such as CDMP into AHLTA.

Project Deviations

Reports in previous fiscal years identified CDMP and related telehealth studies that were being conducted at consortium members' facilities. This report specifically provides an overview of the studies and their progress being conducted at WRAMC. Description of the accomplishments and problems encountered to data collection and/or analyses are identified under the section for each study.

Implementation of Study Manager
Study Manager is currently being used to manage and monitor the progress of three studies being conducted under the direction of COL Vigersky. The primary objective of each study is: 1) Measure the impact of a real-time continuous glucose monitoring (CGM) device on patients with Type 2 diabetes; 2) Determine the impact of a video cell phone reminder system on glycemic control in patients with diabetes mellitus: 3) Determine the impact of a bedside broadband videodevice reminder system on glycemic control in older adults with diabetes mellitus living independently at the Armed Forces Retirement Home. Study manager was also used to manage the data collected for the Genetic Screening in Diabetes study. The purpose of the Genetic Screening study, which is not closed to enrollment was to obtain blood for genetic analysis from patients with diabetes mellitus complicated by nephropathy, autonomic neuropathy, or retinopathy and from their parents and/or siblings in order to determine if any or all of these complications are linked to one or more of the proposed candidate genes.

Study manager will be implemented with additional studies. The diversity of the studies as well as the diversity of personnel managing the studies provides an informal, but comprehensive platform from which to measure the usability and impact of study manager on workflow (efficiency) and effectiveness of data collection. Additionally, in September, 2008, the "architects" of study manager (Sven Bursell, Stephanie Fonda, and Estenda Solutions (Drew Lewis & Richard [RJ] Kedziora) held a focus group to assess the usability of the program. Suggestions to enhance the efficiency of the program were recorded and are being integrated as Study Manager is adapted to new studies. Additionally, a member of the Diabetes Institute (DI) staff at WRAMC has assumed responsibility for adapting study manager to new studies as they are implemented by the DI at WRAMC.

Deployment of JVN Telehealth CDMP application into the Department of Defense HealtheForces. Robert Vigersky MD, and Sven-Erik Bursell PhD
Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005. The Diabetes Institute staff is currently developing the process and procedures for use of the CDMP in their clinic and the Usability/Workflow Study has been completed and findings are being used to further refine CDMP as a case management tool (see #2 above). Recent requirements, however, regarding the elimination of HealtheForces and, consequently interfacing to the Armed Forces Health Longitudinal Technology Application or AHLTA (CHCSII) are currently being investigated. A three-stage plan for integration which was initiated after discussions with representatives of the Office of the Surgeon General of the Army is being modified to be consistent with the Common Development Environment (CDE) being developed by TATRC as a platform for the integration of clinical programs such as CDMP into AHLTA.

A protocol entitled, **"Integration and Assessment of a Diabetes Assessment Tool Kit in AHLTA"**, was approved by the WRAMC Department of Clinical Investigations and CIRO in February 2008, but the CRADA was not approved until May 08. The DATK consists of a risk stratification algorithm for diabetes-related complications and two questionnaires, the Behavior Assessment Tool (BAT) and the Nutrition Assessment Tool – A (NAT-A). The DATK is intended to help providers quickly screen for diabetes-related psychosocial problems (such as smoking, depression, low adherence to recommended appointments, no control of diet, etc.) and clinical problems (such as increased risk of diabetic retinopathy, nephropathy, etc). The DATK is web-based and can "stand-alone", as can its components.

The protocol reflects the modifications required by the CDE. The implementation of this study will serve as one of the first prototypes for the integration of clinical programs into AHLTA. A total of 70 subjects are currently enrolled in this study; 53 enrolled in the period of performance for this report.

Two additional projects, the **Evaluation of Multiple Methods of Viewing and Integration of Glucometer Data through Diabetes Mellitus Everywhere (DME), the Patients' Portal in the Comprehensive Diabetes Management Program (CDMP) into AHLTA,** and **Bi-Directional Merging of the Comprehensive Diabetes Management Program (CDMP) database with AHLTA CDR via the MHS Common Development Environment (CDE),** are continuing the effort initiated by DATK to integrate additional features of CDMP into AHLTA.

The overall aim of the first project, short title, "DME", is to integrate relevant and unique outcomes of the Diabetes Mellitus Everywhere (DME) patient web-based portal into the CDE and evaluate the ease of using DME and accuracy of uploaded data. DME provides patients with a mechanism to upload self-monitored blood glucose (SMBG) data from their homes to their provider for analysis. DME then gives simple statistical and graphical summaries of the SMBG test results as well as electronic diabetes-related information. Enhancing patients' understanding and use of SMBG data together with relevant diabetes education can result in improved glycemic control with a subsequent risk reduction in complications associated with chronically uncontrolled diabetes.

The primary aim of the second project, short title, "Bi-di", is to build a bi-directional interface between the CDMP and the CDE. This interface will

provide an evaluation of how effectively a web-base patient care system can completely integrate with AHLTA by providing data from the AHLTA Central Data Repository (CDR) into the web-based CDMP and taking the calculated information and graphs along with externally collected data, and load that data back into AHLTA. The DI and Estenda Solutions, Inc are working closely with TATRC to: (1) Develop a DHIMS acceptable Requirements Document / Initial System Design Document (SDD) that identifies the needs and requirements for integrating the CDMP and AHLTA databases, (2)Develop the prototype of Telemedicine Tele-Consultation interface within the MHS CDE, (3) Establish a sync-manager process that will, as CPU cycles permit, initiate a process on the site's Local Cache Server (LCS) to grab an XML file generated by the CDMP server and load the AHLTA CDR with the patient's Care Plan, Education Evaluation, Surveys, Personal Biometric Data/Home Monitoring Data (HMBG, BP, Weight), Risk Profile, and JVN non-mydriatic retinal Images and Reports, and (4) Enhance the security model, improving the secure link between the application and Web-services server by implementing the X.509 security certificate which is an ITU-T standard for a public key infrastructure (PKI) for single sign-on and Privilege Management Infrastructure (PMI).

The Diabetes Institute and Estenda Solutions, Inc are working closely with TATRC to accomplish the aims of both "DME" and "Bi-Di". Both projects involve working extensively with the Department of Information Management (DOIM) at WRAMC to gain access to and consequently to meet all the security requirement of that access to the WRAMC network.

Conclusion

Diabetes mellitus is a significant cause of morbidity and mortality in the United States, and the leading cause of new blindness, chronic kidney disease, and non-traumatic amputation in the working-aged American population. Strategies are in place that, based on solid clinical and scientific evidence, can significantly reduce complications of diabetes through timely treatments and appropriate management. Unfortunately, less than 50% of patients with diabetes obtain appropriate medical care. Additionally, there are nearly 8 million Americans with diabetes who are unaware of their condition.

The Joslin Vision Network is a telemedicine initiative that has the potential to bring the highest quality care to all patients with diabetes. The JVN Telehealth program is a web-based interactive telemedicine application that can systematize the organization of disease and care management, that centralizes the patient in the care process, that can impact the ability of diabetic patients to more effectively mange their diabetes, improve their metabolic control, reduce the level of emotional stress associated with managing diabetes, and reduce the incidence of complications through implementation of the CDMP program.

REFERENCES

(These references provide evidence-based peer-reviewed support for JVN Eye Project)

Joslin Vision Network

1. Cavallerano AA, Cavallerano JD, Katalinic P, Tolson AM, Aiello LP, Aiello LM and the Joslin Vision Network Clinical Team. Use of Joslin Vision Network digital-video nonmydriatic retinal imaging to assess diabetic retinopathy in a clinical program. Retina. In press. May 2002

2. Bursell S-E, Cavallerano JD, Cavallerano AA, Clermont AC, Birkmire-Peters D, Aiello LP, Aiello LM, Joslin Vision Network Research Team. Stereo nonmydriatic digital-video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. Ophthalmology 2001;108:572-585.

3. Aiello LM, Cavallerano J, Cavallerano A, Bursell S-E. The Joslin Vision Network (JVN) Innovative Telemedicine Care for Diabetes. Ophtahlmol Clin North Am. 13:2000; 213-224.

4. Aiello LM, Bursell S-E, Cavallerano JD, Gardner WK, Strong J, Joslin Vision Network Research Team. Joslin Vision Network Validation Study: Pilot Image Stabilization Phase. *J Am Optom Assoc* 1998;69:699-710.

5. Kuzmak PM, Dayhoff RE. Extending DICOM Imaging to New Clinical Specialties in the Healthcare Enterprise. VistA Imaging Project, Department of Veterans Affairs, 1335 East West Highway – Third Floor, Silver Spring, MD, USA 20910-3225. peter.kuzmak@med.va.gov

ETDRS

6. Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema; Early Treatment Diabetic Retinopathy Study report number 1. Arch Ophthalmol 1985;103:1796–806.

7. Early Treatment Diabetic Retinopathy Study Research Group. Treatment techniques and clinical guidelines for photocoagulation of diabetic macular edema: Early Treatment Diabetic Retinopathy Study report number 2. Ophthalmology 1987;94:761–74.

8. The Early Treatment Diabetic Retinopathy Study Research Group. Techniques for scatter and local photocoagulation treatment of diabetic retinopathy: Early Treatment Diabetic Retinopathy Study report no. 3. Int Ophthalmol Clin 1987;27:254–64.

9. The Early Treatment Diabetic Retinopathy Study Research Group. Photocoagulation for diabetic macular edema: Early Treatment Diabetic Retinopathy Study report no. 4. Int Ophthalmol Clin 1987;27:265–72.

10. The Early Treatment Diabetic Retinopathy Study Research Group. Case reports to accompany Early Treatment Diabetic Retinopathy Study reports 3 and 4. Int Ophthalmol Clin 1987;27:273–333.

11. Kinyoun J, Barton F, Fisher M, et al, the ETDRS Research Group. Detection of diabetic macular edema: ophthalmoscopy versus photography—Early Treatment Diabetic Retinopathy Study report number 5. Ophthalmology 1989;96:746–51.

12. Early Treatment Diabetic Retinopathy Study Research Group. C-peptide and the classification of diabetes patients in the Early Treatment Diabetic Retinopathy Study. ETDRS Report No. 6. Ann Epidemiol 1993; 3:9–17.

13. Early Treatment Diabetic Retinopathy Study Research Group. Early Treatment Diabetic Retinopathy Study design and baseline patient characteristics: ETDRS report number 7. Ophthalmology 1991;98(5)(Suppl):741–56.

14. Early Treatment Diabetic Retinopathy Study Research Group. Effects of aspirin treatment on diabetic retinopathy: ETDRS report number 8. Ophthalmology 1991; 98(5)(Suppl):757–65.

15. Early Treatment Diabetic Retinopathy Study Research Group. Early photocoagulation for diabetic retinopathy: ETDRS report number 9. Ophthalmology 1991;98(5)(Suppl):766–85.

16. Early Treatment Diabetic Retinopathy Study Research Group. Grading diabetic retinopathy from stereoscopic color fundus photographs—an extension of the modified Airlie House classification: ETDRS report number 10. Ophthalmology 1991;98(5)(Suppl):786–806.

17. Early Treatment Diabetic Retinopathy Study Research Group. Classification of diabetic retinopathy from fluorescein angiograms: ETDRS report number 11. Ophthalmology 1991;98(5)(Suppl):807–22.

18. Early Treatment Diabetic Retinopathy Study Research Group. Fundus photographic risk factors for progression of diabetic retinopathy: ETDRS report number 12. Ophthalmology 1991;98(5)(Suppl):823–33.

19. Early Treatment Diabetic Retinopathy Study Research Groups. Fluorescein angiographic risk factors for progression of diabetic retinopathy: ETDRS report number 13. Ophthalmology 1991;98(5)(Suppl):834–40.

20. Early Treatment Diabetic Retinopathy Study Research Group. Aspirin effects on mortality and morbidity in patients with diabetes mellitus. ETDRS Report No. 14. JAMA 1992; 268:1292-300.

21. Early Treatment Diabetic Retinopathy Study Research Group. Aspirin effects on the development of cataracts in patients with diabetes mellitus. ETDRS Report No. 16. Arch Ophthalmol 1992; 110:339-42.

22. Flynn HW, Chew EY, Simons BD, Barton FB, Remaley NA, Ferris FL III, Early Treatment Diabetic Retinopathy Study Research Group. Pars plana vitrectomy in the early treatment diabetic retinopathy study. ETDRS Report No. 17. Ophthalmology 1992; 99:1351-57.

23. Davis MD, Fisher MR, Gangnon RE, Barton F, Aiello LM, Chew EY, Ferris FL 3rd, Knatterud GL. Risk factors for high-risk proliferative diabetic retinopathy and severe visual loss: Early Treatment Diabetic Retinopathy Study Report #18. Invest Ophthalmol Vis Sci. 1998 39:233-52.

24. Early Treatment Diabetic Retinopathy Study Report Number 19. Focal photocoagulation treatment of diabetic macular edema: Relationship of

treatment effect to fluorescein angiographic and other retinal characteristics at baseline. Arch Ophthalmol 1995;113:1144-1155.

25. Chew EY, Klein ML, Murphy RP, Remaley NA, Ferris FL III, ETDRS Research Group. Early Treatment Diabetic Retinopathy Study Report Number 20. Effects of aspirin on vitreous/preretinal hemorrhage in patients with diabetes mellitus. Arch Ophthalmol 1995:;13:52-55.

26. Chew EY, Klein ML, Ferris FL III, Remaley NA, Murphy RP, Chantry K, Hoogwerf BJ, Miller D, ETDRS Research Group. Early Treatment Diabetic Retinopathy Study Report Number 22. Association of

27. elevated serum lipid levels with retinal hard exudates in diabetic retinopathy. Arch Ophthalmol 1996;114:1079-1084.

28. Fong DS, Segal PP, Myers F, Ferris FL, Hubbard LD, Davis MD, for the Early treatment Diabetic Retinopathy Study research Group. Subretinal fibrosis in diabetic macular edema: ETDRS Report 23. Arch Ophthalmol 1997;115:873-877.

29. Fong DS, Ferris FL 3rd, Davis MD, Chew EY. Causes of severe visual loss in the early treatment diabetic retinopathy study: ETDRS report no. 24. Early Treatment Diabetic Retinopathy Study Research Group. Am J Ophthalmol. 1999;127:137-41.

30. Ferris FL. How effective are treatments for diabetic retinopathy? JAMA 1993; 269:1290-91.

31. Ferris FL, Davis MD, and Aiello LM. Treatment of Diabetic Retinopathy, New England Journal of Medicine 1999;341:9:667-678

DCCT

32. Diabetes Control and Complications Trial Research Group. Are continuing studies of metabolic control and microvascular complications in insulin-dependent diabetes mellitus justified? N Engl J Med 1988; 318:246-50.

33. The Diabetes Control and Complications Trial Research Group. The relationship of glycemic exposure (HbA$_{1c}$) to the risk of development and progression of retinopathy in the Diabetes Control and Complications Trial. Diabetes 1995;44:968-983.

34. The Diabetes Control and Complications Trial Research Group. Progression of retinopathy with intensive versus conventional treatment in the Diabetes Control and Complications Trial. Ophthalmology 1995;102:647-661.

35. The Diabetes Control and Complications Trial Research Group. Hypoglycemia in the Diabetes Control and Complications Trial. Diabetes 1997;46:271-286.

36. The Diabetes Control and Complications Trial Research Group. Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. JAMA 1996;276:1409-1415.

37. The Diabetes Control and Complications Trial Research Group The effect of intensive treatment of diabetes on the development and progression of long term complications in insulin dependent diabetes mellitus. N Engl J Med 1993;329:977-986.

38. The Diabetes Control and Complications Trial Research Group. The relationship of glycemic exposure (HbA$_{1c}$) to the risk of development and progression of retinopathy in the Diabetes Control and Complications Trial. Diabetes 1995;44:968-983.

39. Diabetes Control and Complications Trial/Epidemiology of Diabetes Intervention and Complications Research Group. Retinopathy and nephropathy in patients with type 1 diabetes four years after a trial of intensive therapy. N Engl J Med 2000;342:381-9.

UKPDS

40. Kohner EM, Aldington SJ, Stratton IM, Manley SE, Holman RR, Matthews DR, Turner RC, for the United Kingdom Prospective Diabetes Study. Diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors: United Kingdom Prospective Diabetes Study, 30. Arch Ophthalmol 1998;116:297-303.

41. UK Prospective Diabetes Study Group. Effect of intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes: UKPDS 33. Lancet 1998:352837-853.

Papers Reviewed to provide evidence-based peer-reviewed support for JVN CDMP Project

42. Barrera Jr. M, Glasgow RE, McKay HG, Boles SM, Feil EG. Do Internet-based support interventions change perceptions of social support: An experimental trial of approaches for supporting diabetes self-management. American Journal of Community Psychology 2002, 30: 637-654.

43. Branger PJ, van't Hooft A, van der Wouden JC, Moorman PW, van Bemmel JH. Shared care for diabetes: supporting communication between primary and secondary care. International Journal of Medical Informatics 1999, 53: 133-142.

44. Cherry JC, Moffatt TP, Rodriguez C, Dryden Kirsten. Diabetes disease management program for an indigent population empowered by telemedicine technology. Diabetes Technology and Therapeutics 2002, 4: 783-791.

45. Clark Jr. CM, Synder JW, Meek RL, Stutz LM, Parkin CG. A systematic approach to risk stratification and intervention within a managed care environment improves diabetes outcomes and patient satisfaction. Diabetes Care 2001, 24: 1079-1086.

46. Demakis JG, Beauchamp C, Cull WL, Denwood R, Eisen SA, Lofgren R, Nichol K, Woolliscroft J, Henderson WG. Improving Residents' Compliance With Standards of Ambulatory Care: Results from the VA Cooperative Study on Computerized Reminders. JAMA 2000, 2845: 1411-1416.

47. Dimmick SL, Burgiss SG, Robbins S, Black D, Jarnagin B, Anders M. Outcomes of an integrated telehealth network demonstration project. Telemedicine Journal and e-Health 2003, 9: 13-23.

48. Feil EG, Glasgow RE, Boles S, McKay HG. Who participates in internet-based self-management programs? A study among novice computer users in a primary care setting. The Diabetes Educator 2000, 26: 806-811.

49. Giménez-Pérez G, Gallach M, Acera E, Prieto A, Carro O, Ortega E, González-Clemente JM, Mauricio D. Evaluation of accessibility and use of new communication technologies in patients with type 1 diabetes mellitus. Journal of Medical Internet Research 2002, 4: e16.

50. Glasgow RE, Toobert DJ. Brief, computer-assisted diabetes dietary self-management counseling. Effects of behavior, physiologic outcomes, and quality of life. Medical Care 2000, 38: 1062-1073.

51. Glawgow RE, La Chance PA, Toobert DJ, Brown J. Hampson SE, Riddle MC. Long term effects and costs of brief behavioural dietary intervention for patients with diabetes delivered from the medical office. Patient Education and Counseling 1997, 32: 175-184.

52. Glasgow RE, Toobert DJ, Hampson SE. Effects of a brief office-based intervention to facilitate diabetes dietary self-management. Diabetes Care 1996, 19: 835-842.

53. Iafusco D, Ingenito N, Prisco F. The chatline as a communication and educational tool in adolescents with insulin-dependent diabetes: Preliminary observations. Diabetes Care 2000, 23: 1853.

54. Johnston B, Weeler L, Deuser J, Sousa KH. Outcomes of the Kaiser Permanente Tele-Home Health Research Project. Archives of Family Medicine 2000, 9: 40-45.

55. Kirkman SM, Weinberger M, Landsman PB, Samsa GP, Shortliffe EA, Simel DL, Feussner JR. A telephone-delivered intervention for patients with NIDDM. Diabetes Care 1994, 17: 840-845.

56. Lobach DF, Hammond, WE. Computerized decision support based on a clinical practice guideline improves compliance with care standards. American Journal of Medicine 1997, 102: 89-98.

57. McKay HG, King D, Eakin EG, Seeley JR, Glasgow RE. The Diabetes Network internet-based physical activity intervention: A randomized pilot study. Diabetes Care 2001, 24: 1328-1334.

58. McKay HG, Glasgow RE, Feil EG, Boles SM, Barrera Jr. M. Internet-based diabetes self-management and support: Initial outcomes from the Diabetes Network Project. Rehabilitation Psychology 2002, 47: 31-48

59. Meigs JB, Cagliero E, Dubey A, Murphy-Sheehy P, Gildesegame C, Chueh H, Barry MJ, Singer DE, Nathan DM. A controlled trial of web-based diabetes disease management. Diabetes Care 2003, 26: 750-757.

60. Montori VM, Dinneen SF, Gorman CA, Zimmerman BR, Rizza RA, Bjornsen SS. The impact of planned care and a diabetes electronic management system on community-based diabetes care: The Mayo Health System Diabetes Translation Project. Diabetes Care 2002, 25: 1952-1957.

61. Patel VL, Kushniruk AW, Yang S, Yale JF. Impact of a computer-based patient record system on data collection, knowledge organization, and reasoning. Journal of the American Medical Informatics Association 2000, 7: 569-585.

62. Peters A, Davidson MB. Application of a diabetes managed care program: The

feasibility of using nurses and a computer system to provide effective care. Diabetes Care 1998, 21: 1037-1043.

63. Piette JD. Patient education via automated calls. A study of English and Spanish
    speakers with diabetes. American Journal of Preventive Medicine 1999, 17: 138-141.

64. Piette JD, Mah CA. The feasibility of automated voice messaging as an adjunct to
    diabetes outpatient care. Diabetes Care 1997; 15-21.

65. Piette JD, McPhee SJ, Weinberger M, Mah CA, Kraemer FB. Use of automated telephone disease management calls in an ethnically diverse sample of low-income patients with diabetes. Diabetes Care 1999, 22: 1302-1309.

66. Piette JD, Weinberger M, McPhee SJ, Mah CA, Kraemer FB, Crapo LM. Do automated calls with nurse follow-up improve self-care and glycemic control among vulnerable patients with diabetes? American Journal of Medicine 2000, 108: 20-27.

67. Piette JD; Weinberger M, Kraemer FB, McPhee SJ. Impact of automated calls with nurse follow-up on diabetes treatment outcomes in a Department of Veterans Affairs health care system: A randomized controlled trial. Diabeted Care 2001, 24: 202-208.

68. Smith L, Weinert C. Telecommunication support for rural women with diabetes.
    Diabetes Educator 2000; 26: 645-655.

69. Sperl-Hillen J, O'Connor PJ, Carlson RR, Lawson TB, Halstenson C, Crowson T,
    Wuorenma J. Improving diabetic care in a large health care system: An enhanced primary care approach. Journal on Quality Improvement 2000; 26: 615-622.

70. Tai SS, Nazareth I, Donegan C, Haines A. Evaluation of general practice computer templates. Lessons from a randomized controlled trial. Methods of Information in Medicine 1999; 38: 177- 181.

71. Zrebiec JF, Jacobson AM. What attracts patients with diabetes to an internet
    support group? A 21-month longitudinal website study. Diabetic Medicine 2001; 18: 154-158.

Appendix A

The CDMP is a web-based diabetes case management tool developed by a consortium of researchers, physicians, and educators specializing in diabetes and its management. The consortium was drawn from the Joslin Diabetes Center, the Department of Defense [Walter Reed Army Medical Center (WRAMC) and Tripler Army Medical Center (TAMC)], Veterans Health Affairs (Boston Veterans Hospital), and the Indian Health Service (IHS). The overall goal behind the development of the CDMP is to provide an interactive, web-based clinical tool for care managers that improves diabetes care. The CDMP is intended to: provide an automatic system to foster a high level of continuous care and communication among patients, care managers, and physicians; insure that the latest clinical guidelines are used in the care; and focus on *both* clinical and behavioral patient problem areas, rather than just clinical areas, as is usually the case in diabetes care.

The standard clinical care for a patient with diabetes typically follows a pattern similar to that outlined below:
1) Patient assessment by review of medical records and lab reports, taking a medical history, and performing a physical examination;
2) Assessment of the physical, psychological, and learning status of the patient (via formal or informal interviewing techniques and/or exams);
3) Preparation and maintenance of a treatment plan for the patient, with an emphasis on patient self-management;
4) Referral of patient needing immediate medical care for non-diabetic problems to his/her primary care provider (PCP) or identification of a PCP for any patient who does not have one;
5) Referral of the patient to consultants (e.g. ophthalmology, cardiology, and nephrology) as needed;
6) Referral of the patient to diabetes education services, including classes, booklets, and other media;
7) Ongoing follow-up and feedback to the patient and treatment providers.

By contrast, the CDMP was designed to contribute to the standard clinical process by:
1) Generating three levels of alerts for the care manager or provider, all of which are based on a risk assessment algorithm and American Diabetes Association (ADA) and Diabetes Institute (DI) diabetes management guidelines (see below) in advance of the clinic visit;
2) Providing clinical assessment, notification, and communication tools;
3) Tracking availability and patient use of educational resources that are site and user specific;
4) Summarizing patient knowledge and the impact of educational interventions;
5) Providing dynamic care planning which is done with the patient and targets physical wellness, lifestyle self-management, and psychosocial health (including possible patient barriers in these areas);
6) Connecting with the health organization's health information system or available electronic data (with provisions for client and medical records privacy).

The CDMP is based on current ADA clinical practice guidelines (CPGs) and those of the Diabetes Institute of the WRHCS. They focus on diabetes clinical management, lifestyle modification and psychosocial health. In the CDMP case management model, the care manager is the key coordinator between patients and

the healthcare team that includes MDs, NPs, educators, sub-specialists, nutritionists, and behavioral clinicians.

The CDMP is designed to be superimposed functionally and integrated into the HealtheForces Integrated Clinical Data Base (ICDB) until it is de-commissioned and then into CHCS II. There is a CDMP server housed in the Department of Information Management, WRAMC.

CDMP generates "alerts" when a patient has experienced a particular health event or when the results from a patient's test exceed a pre-determined clinical threshold. Alerts are presented to the care manager/provider on his/her home page when next s/he logs into ICDB. The alerts are "red" (high risk), "yellow" (medium risk), and "green" (low risk) icons and are based on the CPGs. Selecting the alert icon activates search options specific to the patient; e.g., demographic data, medication list, laboratory results, the event or result that generated the alert, available options for the care plan, and follow-up actions. These are displayed with a pull-down menu from which the care manager/provider can select various actions to be taken in response to the alert.

The CDMP also provides an overall clinical risk stratification of each patient. The stratification indicates whether and how the patient is above or below established goals in the areas of glycemic control, nephropathy, peripheral vascular disease, peripheral neuropathy, and retinopathy. Together with the care manager's/provider's knowledge of his/her patient, the risk stratification allows the care manager/provider to devise an individualized care plan that includes recommendations regarding the patient's goals, lifestyle, monitoring needs, and areas requiring further education. The risk stratification indicates whether patients are "high risk", "moderate risk", or "low risk" based on the Joslin Diabetes Center Clinical Guidelines for Adults with Diabetes.

CDMP has a section on patient education. This section lists the educational tools available at a particular site (e.g., videos, books, classes) and provides an evaluation of how advanced each tool is. The care manager and/or the diabetes educator can then assign educational tools, track each patient's use of the tools, and thus obtain a summary of a patient's knowledge and the impact of the educational intervention.

The CDMP contains other features intended to assist the care manager/provider in the organization of his/her caseload. For example, the CDMP home page shows the care manager's/provider's daily reminders. The reminders show the patient's name, the type of reminder needed (e.g., clinical assessment, modification of the care plan, etc.), and pertinent details regarding the reminder such as type of action needed. The CDMP home page also shows each day's upcoming appointments. Further, there is a scheduler within the CDMP that helps care managers to schedule routine appointments. Finally, the CDMP provides the care manager/provider easy access to complete, and/or up-to-date paperless records of each patient in his/her caseload. For each patient, these records include a history of his/her behavioral assessment, a photograph, demographics and vital signs, medication usage, record of laboratory results, health care procedures the patient has had, diagnoses, patient admission history, education history, and the results (if performed) of the non-dilated retinal examination using the Joslin Vision Network digital, stereo non-mydriatic cameras. The Joslin Vision Network is already located in 4 sites in the Walter Reed Health Care System (WRAMC, Kimbrough Ambulatory Care Center, Dewitt Army Community Hospital, and Fairfax Family Health Clinic), so this

information will be included in the CDMP at the Diabetes Institute when it is
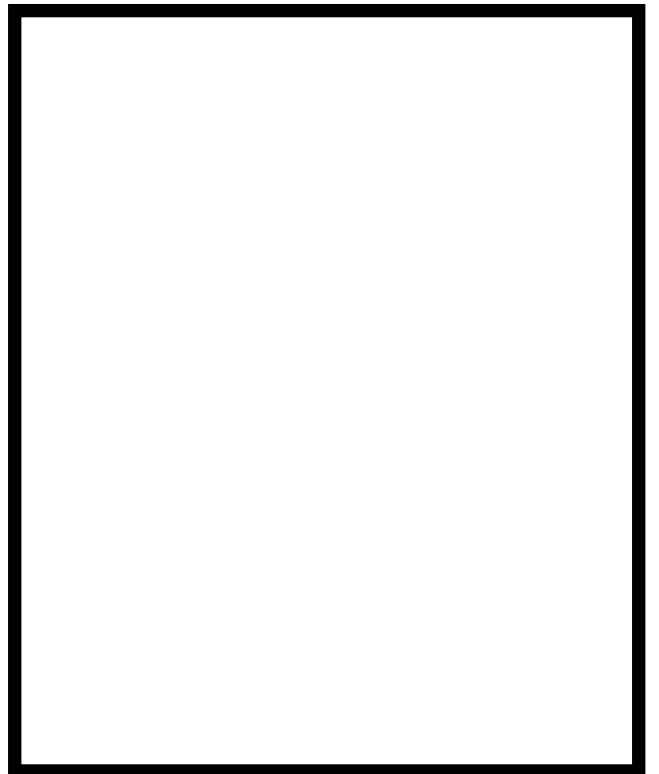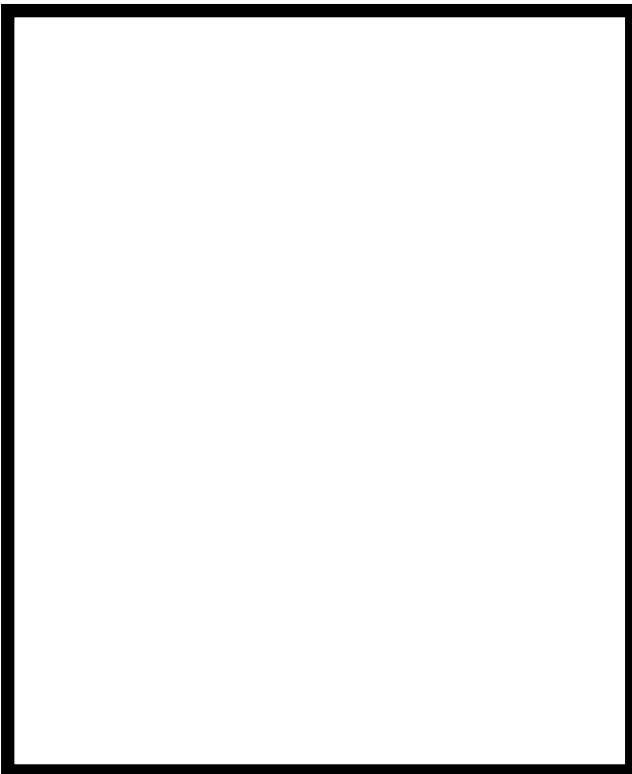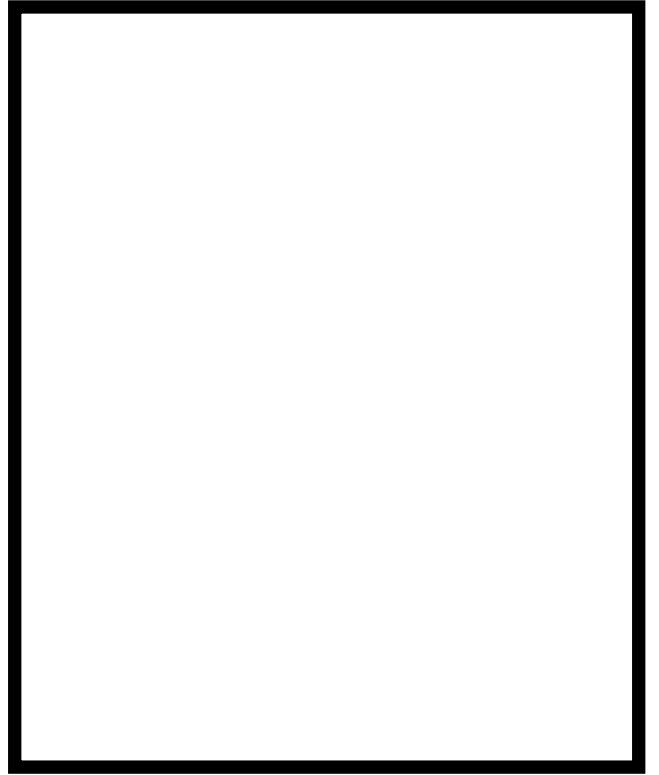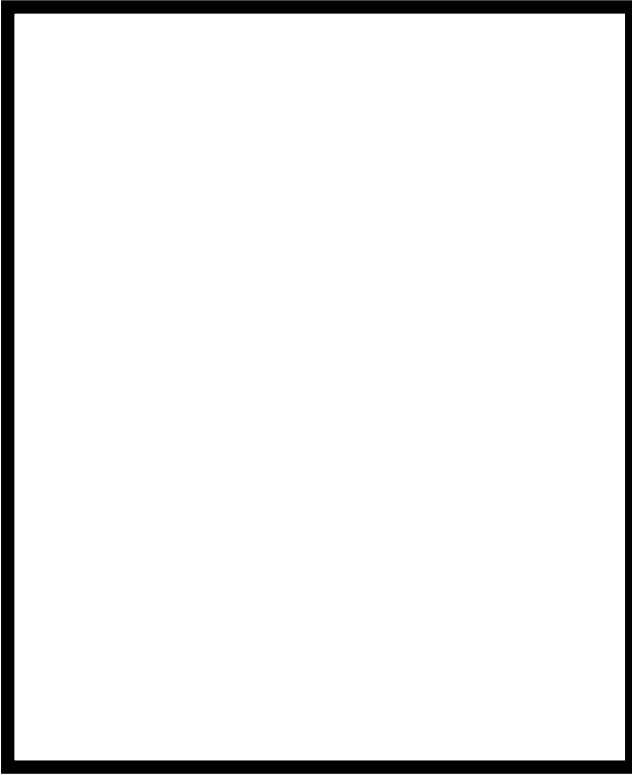deployed.

Appendix B

SECTION A. CLOCK DRAWING EXERCISE

Please read and do the following carefully:

- *In the blue box on the next page:*
- *Draw a picture of a clock*
- *Put in all the numbers*
- *Set the time to ten after eleven*

Hand this sheet back and go to the next page

SECTION B. BACKGROUND INFORMATION

1. **What is your date of birth?**

   ☐☐ / ☐☐ / ☐☐☐☐
   M   M   D   D   Y   Y   Y   Y

2. **Are you male or female?**

   Male

   O   Female

3. **Do you consider yourself to be Spanish, Hispanic, or Latino (Latina)?**

   Yes

   O   No

4. **What race do you consider yourself to be? Select one or more of the following:**

	Yes	No
a. American Indian or Alaska Native	O	O
b. Asian	O	O
c. Black or African American	O	O
d. Native Hawaiian or other Pacific Islander	O	O
e. White or Caucasian	O	O
f. OTHER	O	O
f1. SPECIFY		

5. **What is the highest grade or level of school you have completed or the highest degree you have received?**

   O   Less than high school

   O   High school diploma (including GED)

   O   Some college

   O   College degree (including Associate's or
               Bachelor's Degree)

   O   Some graduate school

O   *Graduate or professional degree (including MA;*
MS; Master's, MBA, Law and MD, PhD)

6.   **How many people, including yourself, are supported on your household's income?**   *# PEOPLE*

7.   **Including income from wages, salaries, Social Security or retirement benefits, help from relatives, veteran's benefits, real estate, investments, and other sources, about how much was your total <u>household income</u> in the last 12 months?**

O   *Less than $5,000*

O $5,000 - $9,999

O $10,000 - $19,999

O $20,000 - $29,999

O $30,000 - $39,999

O $40,000 - $49,999

O $50,000 - $59,999

O $60,000 - $69,999

O $70,000 - $79,999

O $80,000 - $89,999

O $90,000 - $99,999

O $100,000 or more

O   Don't know

8.   **Are you currently covered by public (e.g., Medicare, Medicaid) or private (e.g., through your or your spouses' job, etc.) health insurance?**

     Yes

O

O   *No*

SECTION C. BEHAVIORAL ASSESSMENT TOOL

Bat Study Questionnaire	STUDY PARTICIPANT ID			
	DATE			
		/		/	
	M	M	D	D		Y	Y

1. *Is English your native language?*

    O   No   Go to next question
    O   Yes   *Skip to question # 3*

2. *When you learn something new, does it help to hear it in your native language?*

    O   Yes
    O   No
    O
         Don't know or not sure

3. *Would you like someone who speaks your native language to help you complete this survey?*

    O   Yes
    O   No
    O
         Don't know or not sure

4. *Do you have problems reading and understanding written materials?*

    O   Yes   Go to next question
    O   No   *Skip to question #6*
    O   Don't know or not sure

5. *Would you like someone to read the survey questions to you?*

    O   Yes
    O   No
    O
         Don't know or not sure

Diabetes History

6. *When were you first told you have diabetes?*

      O   *I was just diagnosed within the last 12 months*

      O   *1 - 5 years ago*

      O   *6 - 10 years ago*

      O   *More than 10 years ago*

      O

               Don't know or not sure

Nutrition

7. *On a typical day, how many servings of fruits and vegetables do you eat?*

      O   *None*

      O   *1 - 5 servings*

      O   *6 – 10 servings*

      O   *More than 10 servings*

      O

               Don't know or not sure

8. *During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?*

      O   *0 days*

      O   *1 - 5 days a week*

      O   *6 - 7 days a week*

      O

               Don't know or not sure

9. *How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?*

      O   *0 times*

      O   *1 - 2 times*

      O   *3 - 5 times*

      O   *6 or more times*

      O

               Don't know or not sure

Physical Activity

10. *How would you describe your physical activity level?*

O   Sedentary or lightly active (Mostly sitting or lying down, e.g., TV, reading; Sitting or standing most of the day, e.g., desk work, teaching, white collar work, light housework)

O   Moderately active (Standing or walking, moving most of the day, e.g., heavy housework, brisk walking, gardening)

O   Very active (Moving strenuously, e.g., aerobics, biking, hiking, running, climbing stairs, mowing lawn, manual labor)

O
     Don't know or not sure

11. *In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more?*

O   0 times

O   1 - 3 times

O   4 - 6 times

O   More than 6 times

O
     Don't know or not sure

Checking Blood Sugars

12. *How often do you check your blood sugar?*

O   Never

O   Less than once a week

O   1 - 5 days a week

O   About once a day

O   Twice a day or more

O
     Don't know or not sure

Medications

13. In the last 7 days, how often did you miss taking your diabetes pills or insulin?

O   One time a week

O   2 - 4 times a week

O   Most days

O   Everyday

Mood

14.   During the past month have you often been bothered by feeling down, depressed, or hopeless?

O   *Yes*

O   *No*

O
         Don't know or not sure

15. *During the past month have you often had little interest or pleasure in doing things?*

     O   *Yes*

     O   *No*

     O

     Don't know or not sure

Alcohol

16. *Do you drink alcohol?*

     O   *Yes*

     O   *No*

> **Go to next question**
> **Skip to question #18**

17. *Are you concerned about your drinking?*

     O   *Yes*

     O   *No*

Smoking

18. *Do you smoke cigarettes, cigars, a pipe, or chew tobacco?*

     O   *Yes*

     O   *No*

     O   *No, but I quit within the last 6 months*

Your health

19. *In general, would you say your health is:*

     O   *Excellent*

     O   *Very Good*

     O   *Good*

     O   *Fair*

     O   *Poor*

20. *Have you been examined by an eye doctor in the last 12 months?*

     O   *Yes*

     O   *No*

     O

     Don't know or not sure

21. *How often do you check your feet for sores, cuts, or bruises?*

    O   *Never*

    O   *Once a month*

    O   *Every couple of weeks*

    O   *At least once a week*

    O   *Every day*

    O
        Don't know or not sure

22. *Have your feet been examined by a doctor in the last 12 months?*

    O   *Yes*

    O   *No*

    O
        Don't know or not sure

23. *Do you use other healing methods or remedies in addition to those prescribed for you?*

    O   *Yes*

    O   *No*

    O
        Don't know or not sure

Support from Family and Friends

24. *Do you have family and friends you can ask for help?*

O	*Yes*	**Go to next question**
O	*No*	**Skip to question #26**
O	Don't know or not sure	**Skip to question #26**

25. *Do your family and friends live in your house or nearby?*

    O   *Yes*

    O   *No*

    O
        Don't know or not sure

26.   *Do you agree with the following statement? My family and friends support me by encouraging me to do things to improve my health.*

      O   *Strongly agree*

      O   Agree

      O   *Neither agree nor disagree*

      O   *Disagree*

    O   *Strongly disagree*

Coming to the clinic

27.   *Do you have problems getting to the clinic?*

      O   *Yes*

      O   *No*

28.   *How long does it usually take you to get to the clinic?*

      O   *Less than 30 minutes*

      O   *30 minutes to an hour*

      O   *More than an hour*

      O   *Don't know or not sure*

29.   *How do you usually get to the clinic?*

      O   *My family or a friend drives me*

      O   *I drive myself*

      O   *I ride a van or bus or train*

      O   *I walk or ride a bicycle*

      O   *Other*

Education

30.   *How do you like to learn about new things?*

	Yes	**No**
a. *Watching slides or videos*	O	O
b. *Reading*	O	O

c.	Others showing me how	O	O
d.	Discussions	O	O
e.	Listening to others	O	O
f.	Using computers	O	O
g.	In a class	O	O
h.	Other ways	O	O

31. *How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?*

       O   *A lot*

       O   *Some*

       O   *None*

       O   *Don't know or not sure*

32. *Would you like to learn more about taking care of your diabetes?*

       O   *Yes*

       O   *No*

       O   *Don't know or not sure*

More About You

33. *Which **BEST** describes you? (Choose only one answer.)*

       O   *Employed full-time*

       O   *Employed part-time*

       O   *Disabled*

       O   *Retired*

       O   *Student*

       O   *Looking for work*

       O   Other

34. *Do you have any vision problems?*

       O   *Yes*

       O   *No*

       O   *Don't know or not sure*

35. *Do you have any hearing problems?*

       O   *Yes*

O   *No*

O
         Don't know or not sure

36.   *Do you have any problems walking?*

     O   *Yes*

     O   *No*

     O
         Don't know or not sure

37.   *Do you have problems remembering things?*

     O   *Yes*

     O   *No*

     O
         Don't know or not sure

38.   *Do you have any money issues that affect your ability to take care of any of the following items?*

		Yes	**No**
a.	*Medication*	O	O
b.	*Food*	O	O
c.	*Transportation*	O	O
d.	*Self-monitoring supplies*	O	O

39.   *Do you have any concerns about your diabetes that we have not covered today? If you check yes, someone from the staff will talk to you about them. (NOTE: QUESTION WILL NOT BE ASKED FOR THIS STUDY)*

     O   *Yes*

     O   *No*

     O   Don't know or not sure

SECTION D. FINAL QUESTION

1.   *Did you complete these questions with help from another person?*

        O   *Yes*

        O   *No*

        O   *Don't know or not sure*

Appendix C.1
Behavioral Assessment Tool Questions

Note that the format of the questionnaire will be different in the PureEdge Forms. These forms are not completed yet, so we cannot show them here.

Name:	Last 4 of your SSN:

1. Is English your native language?
2. When you learn something new, does it help to hear it in your native language?
3. Would you like someone who speaks your native language to help you complete this survey?
4. Do you have problems reading and understanding written materials?
5. Would you like someone to read the survey questions to you?
Diabetes History
6. When were you first told you have diabetes?
Nutrition
7. On a typical day, how many servings of fruit and/or vegetables do you eat?
8. During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?
9. How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?
Physical Activity
10. How would you describe your physical activity level?
11. In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more (e.g., heavy housework, brisk walking, gardening, aerobics, biking, hiking, running, climbing stairs, mowing the lawn, manual labor)?
Checking Blood Sugars
12. How often do you check your blood sugar?
Medications
13. In the last 7 days, how often did you miss taking your diabetes pills or insulin?
Mood
14. During the past month, have you often been bothered by feeling down, depressed, or hopeless?
15. During the past month, have you often had little interest or pleasure in doing things?
Alcohol
16. Do you drink alcohol?
17. Are you concerned about your drinking?
Smoking
18. Do you smoke cigarettes, cigars, a pipe, or chew tobacco?
Your health
19. In general, would you say your health is:
20. Have you been examined by an eye doctor in the last 12 months?
21. How often do you check your feet for sores, cuts, or bruises?
22. Have your feet been examined by a doctor in the last 12 months?
23. Do you use other healing methods or remedies in addition to those prescribed for you?
Support from friends and family
24. Do you have family and friends you can ask for help?
25. Do your friends and family live in your house or nearby?
26. Do you agree with the following statement? My family and friends support me by encouraging me to do things to improve my health.
Coming to the clinic
27. Do you have problems getting to the clinic?

28. How long does it usually take you to get to the clinic?
29. How do you usually get to clinic?
Education
30. How do you like to learn about new things?
31. How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?
32. Would you like to learn more about taking care of your diabetes?
More about you
33. Which best describes you? (question pertains to employment status)
34. Do you have any vision problems?
35. Do you have any hearing problems?
36. Do you have any problems walking?
37. Do you have problems remembering things?
38. Do you have any money issues that affect your ability to take care of any of the following items: medication, food, transportation, and self-monitoring supplies?
39. Do you have any concerns about your diabetes that we have not covered today? If you check yes, someone from the staff will talk to you about them.

Appendix C.2
Nutritional Assessment Tool -- A

Note that the format of the questionnaire will be different in the PureEdge Forms. These forms are not completed yet, so we cannot show them here.

Name: **Last 4 of your SSN:**

Question	Answer
Have you seen a Dietitian (or Nutritionist) for your diabetes within the last 12 months?	Yes / No / I don't know
Do you have any religious, cultural, or personal beliefs that should be part of your diabetes care?	Yes / No
Do you have any food allergies or intolerances?	Yes / No
Do you take Vitamins, Herbs, minerals or any other supplements?	Yes / No
Who does most of the food shopping for the home?	1. Self only 2. Spouse or Significant Other only 3. Self and another person 4. Community/Home Health Worker only 5. Other
Who prepares most of the meals at home?	1. Self only 2. Spouse or Significant Other only 3. Self and another person 4. Community/Home Health Worker only 5. Other
How many times per week do you eat your main or big meal away from home (e.g. takeout, café/restaurant, friend's or family's home, Elder Center, etc.)?	1. 0-1 times per week 2. 2-3 times per week 3. More than 3 times per week
How satisfied are you with how you are managing your eating plan?	1. Not at all satisfied 2. Somewhat satisfied 3. Very satisfied 4. Don't have an eating plan
Does your mood affect your eating habits?	Yes / No
If you have ever tried to make changes in what you eat, how successful were you?	1. Not at all successful 2. Somewhat successful 3. Very successful 4. Never tried to make changes
Would you like information about any of these topics? Check boxes:	1. Avoiding Hypoglycemia 2. Avoiding Hyperglycemia 3. Meal Planning for Diabetes 4. Choosing Healthy Snacks 5. Eating Away From Home 6. Managing Diabetes during Holidays and Celebrations 7. Grocery Shopping and Food Labels 8. Modifying Recipes 9. Losing Weight 10. Physical Activity 11. Eating for a Healthy Heart 12. Eating to Keep Your Kidneys Healthy 13. Other topics for your CareTeam?

Appendix C.3

Risk Stratification Algorithm and Report for Fictitious Patient